

(2) Recombinant and/or synthetic nucleic acids that encode for the functional forms of any overlap toxin listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*; or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) Overlap select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any overlap select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Nonviable overlap select agents or nonfunctional overlap toxins.⁵

(3) Any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can identify that the agent is within the exclusion category.

(e) An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or modified toxin does not pose a severe threat to public health and safety, animal health, or animal products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at <http://www.selectagents.gov/>.

(2) If an excluded attenuated strain or modified toxin is subjected to any

manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

(f) Any overlap select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process.

(2) The Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin.

(3) The Federal law enforcement agency reports the seizure of the overlap select agent or toxin to APHIS or CDC.

(i) The seizure of any of the following overlap select agents and toxins must be reported within 24 hours by telephone, facsimile, or e-mail: *Bacillus anthracis*, *Burkholderia mallei*, or *Burkholderia pseudomallei*. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after seizure of the overlap select agent or toxin.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(4) The Federal law enforcement agency reports the final disposition of the overlap select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for 3 years.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008; 77 FR 61078, Oct. 5, 2012; 79 FR 26830, May 12, 2014]

§ 121.5 Exemptions for VS select agents and toxins.

(a) Diagnostic laboratories and other entities that possess, use, or transfer a

in paragraphs (c)(1) through (c)(3) of this section may be subject to the permit requirements under part 122 of this subchapter.

⁵However, the importation and interstate movement of these nonviable overlap select agents may be subject to the permit requirements under part 122 of this subchapter.

§ 121.5

9 CFR Ch. I (1–1–16 Edition)

VS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification, the agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin is reported to APHIS or CDC.

(i) The identification of any of the following select agents and toxins must be immediately reported by telephone, facsimile, or e-mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), classical swine fever virus, foot-and-mouth disease virus, virulent Newcastle disease virus, rinderpest virus, or swine vesicular disease virus. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification.

(ii) For all other VS select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification.

(iii) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(iv) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(b) Diagnostic laboratories and other entities that possess, use, or transfer a VS select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 90 calendar days of receipt, the agent or toxin is transferred in accordance with § 121.16 or de-

stroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin, and its derivative, is reported to APHIS or CDC. To report the identification of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 days of receipt of the agent or toxin. A copy of the completed form must be maintained for 3 years.

(c) Diagnostic reagents and vaccines that are, bear, or contain VS select agents or toxins that are produced at USDA diagnostic facilities will be exempt from the requirements of this part.

(d) Unless the Administrator by order determines that additional regulation is necessary to protect animal health or animal products, products that are, bear, or contain VS select agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

(e) The Administrator may exempt from the requirements of this part an experimental product that is, bears, or contains a VS select agent or toxin if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal health or animal products. To apply for an exemption, an individual or entity must submit APHIS/CDC Form 5. A written decision granting or denying the exemption will be issued. The applicant

must notify APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(f) In addition to the exemptions provided in paragraphs (a) through (e) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal health or animal products. An individual or entity may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008; 77 FR 61078, Oct. 5, 2012; 79 FR 26831, May 12, 2014]

§ 121.6 Exemptions for overlap select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator or the HHS Secretary, within 7 calendar days after identification, the agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and

any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin is reported to APHIS or CDC.

(i) The identification of any of the following overlap select agents and toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis*, *Burkholderia mallei*, or *Burkholderia pseudomallei*. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification.

(iii) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(iv) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator or the HHS Secretary, within 90 days of receipt, the agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin, and its derivative, is reported to APHIS or CDC. To report the identification of an overlap select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for 3 years.

(c) Unless the Administrator by order determines that additional regulation of a specific product is necessary to